

R E M A R K S

Applicants note that all amendments and cancellations of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),¹ and without waiving the right to prosecute the amended or cancelled Claims (or similar Claims) in the future.

In the Final Office Action mailed February 8, 2011, the Examiner objected to Claim 3 because because the deposit assigned accession number KCCM-10557 relates to a *E. coli* host cell, rather than a vector. Applicants have amended Claim 3 to recite that the transformant is *Escherichia coli* DH5 α CJ2004 having accession number KCCM-10557. As such, applicants respectfully request that the objection be withdrawn.

The Examiner further objected to Claims 1, 2, 4 and 5 due to the phrase “an isolated polynucleotide as set forth in SEQ ID NO:1.” Applicants have amended the claims to recite “an isolated polynucleotide comprising the nucleotide sequence of SEQ ID NO:1” as suggested by the Examiner. As such, applicants respectfully request that the objection be withdrawn.

In the Final Office Action mailed February 8, 2011, the Examiner issued several rejections. Each of the rejections is discussed in detail below.

I. The Claims are Definite

The Examiner rejects Claims 7-9 under 35 U.S.C. 112, second paragraph, as allegedly indefinite. In particular, the Examiner states that “Claim 7 is incomplete for omitting essential steps....” (Office Action, pg. 5). Applicants respectfully disagree. Nonetheless, in order to further the business interests of the applicants, and without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), and without waiving the right to prosecute the amended claims (or similar claims) in the future, applicants have amended Claim 7 to recite the method steps of cultivating the transformant in a culture medium; obtaining a protein crude extract comprising γ -butyrobetaine hydroxylase from the culture medium; incubating the

protein crude extract and γ -butyrobetaine in a reaction buffer; and collecting L-carnitine from the reaction buffer. Accordingly, applicants submit that the claims include all essential steps and are thus definite.

The Examiner rejects Claim 9 as allegedly indefinite because the deposit assigned accession number KCCM-10557 relates to a *E. coli* host cell, rather than a vector. Applicants respectfully disagree. Nonetheless, in order to further the business interests of the applicants, and without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), and without waiving the right to prosecute the amended claims (or similar claims) in the future, applicants have amended Claim 9 to recite that the transformant is *Escherichia coli* DH5 α CJ2004 having accession number KCCM-10557.

Accordingly, applicants submit that the claims are definite and respectfully request that the rejections be withdrawn.

II. The Claims are Enabled

The Examiner rejects Claims 7-9 under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement. In particular, the Examiner states that the specification “while being enabling for a method for producing L-carnitine comprising cultivating a *Escherichia coli* bacterium...does not reasonably provide enablement for other transformants, or other methods of preparing L-carnitine using a γ -butyrobetaine hydroxylase.” (Office Action, pgs. 6-7). Applicants respectfully disagree. As described above, the claims have been amended to recite the specific steps of using the disclosed transformant to express γ -butyrobetaine hydroxylase and generate and collect L-carnitine. The specification (e.g., on pages 10-11) teaches a variety of host cells for expression of γ -butyrobetaine hydroxylase. One of skill in the art would understand how to select and test host cells. Accordingly, applicants submit that the claims are enabled and respectfully request that the rejection be withdrawn.

III. The Claims are Supported by Adequate Written Description

The Examiner rejects Claims 7-9 under 35 U.S.C. 112, first paragraph, as allegedly lacking written description. Applicants respectfully disagree. As described

above, the claims have been amended to recite the specific steps of using the disclosed transformant to express γ -butyrobetaine hydroxylase and generate and collect L-carnitine. The specification (e.g., on pages 10-11) lists a variety of host cells for expression of γ -butyrobetaine hydroxylase. Accordingly, applicants submit that the claims are supported by written description and respectfully request that the rejection be withdrawn.

CONCLUSION

If a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call the undersigned collect at (608) 662-1277.

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